

REMARKS/ARGUMENTS

Claims rejection under 35 U.S.C. section 112: Claims 1-5 have been amended as suggested by the Examining Officer by replacing the word “preventing” with the words “reducing the incidence of”.

Claims 1-5 were rejected under 35 U.S.C. 112 second paragraph. Examiner Goldberg required that the original patent application be separated into two separate applications because they included two different classes of compounds. The only compounds to be listed in the specifications of this patent application are Methysticin, Dihydromethysticin and 5,6-Dehydromethysticin as noted in the previous office action dated 03-04-2003 as required by Examiner Goldberg.

Claims 2-5 have been amended as suggested by the examining officer replacing “comprising” with “in which the composition is”.

Claims rejection under 35 U.S.C. section 102 (a): Claim 1 was rejected under 35 U.S.C. 102(b), now corrected to 35 U.S.C. 102(a) as being anticipated by CAPLUS DN 131:298760 (Fujiki). In November 1999 Fujiki published a paper on cancer prevention and green tea. In his paper he discusses how green tea and specifically extracts of green tea act as cancer preventive agents. He presents information on how green tea extracts inhibit cancer cells and induce apoptosis. At the end of his article he introduces kava as a beverage consumed in a country that has a low cancer incidence rate. He presents no information that links kava with the reduction in the cancer incidence rate. Moreover he admits that he has not done any research to support his

contention that kava is related to the cancer incidence rate when he states “We are now studying whether kava lactones can inhibit cancer development in the lung, in rodent carcinogenesis experiments.” It is obvious that by this statement he only knows that Fiji has a low cancer incidence rate and they drink kava. His laboratory is planning to study kava in rodent cancer cells to determine if kava has any cancer preventive properties. With the rodent studies not yet started he admits to have no scientific basis for kava as a cancer chemopreventive agent. Fujiki never states that kava is responsible for the reduced incidence of cancer in Fiji.

Dr. Steiner was researching the medicinal properties beginning in 1997. Earlier in 1997 Dr. Steiner began evaluating kava as an anticraving agent for the treatment of addictions. That work has now resulted in the approval of the issuance of a patent for kava as an anticraving agent for alcohol. As a result of his research on kava as an anticraving agent, his knowledge of the cultures that consume kava and the research in Hawaii involving cancer incidence rates in the Pacific he was led to see if there was a correlation between kava and the low cancer incidence rates in the Pacific. Work on kava as a cancer chemopreventive agent was begun by Steiner in November of 1997 as evidenced by his Declaration under 37 C.F.R. 1.131. It is clear that Steiner completed his research long before Fujiki began to collect data. The declaration includes journal entries on the development of kava as a cancer chemopreventive agent and a copy of an organizational flow chart that outlines that the research and development of kava as a cancer chemopreventive agent predicated the clinical research on kava as a anticraving agent that was done in June of 1999.

Claims rejection under 35 U.S.C. section 103(a)

Claims 1-5 were rejected under 35 U.S.C. 103(a) as being unpatentable over CAPLUS DN 131:298760 (Fujiki). In the cited reference Fujiki states that people who drink green tea have

lower cancer incidence rates. Fujiki does not disclose that kava reduces the incidence of cancer. While he provides extensive data to support his claim that green tea reduces cancer incidence he only states that people in Fiji have low cancer incidence rates and that kava is consumed in Fiji. He never states that people who consume kava have low cancer incidence rates. He provides no data to link kava as the etiologic factor in reducing the cancer incidence rate. He is merely stating that kava is consumed in a country with low cancer incidence. Fujiki never states that kava is responsible for the reduced incidence of cancer in Fiji. Fujiki also clearly states that he has done no research into whether kava is effective in reducing the incidence of cancer.

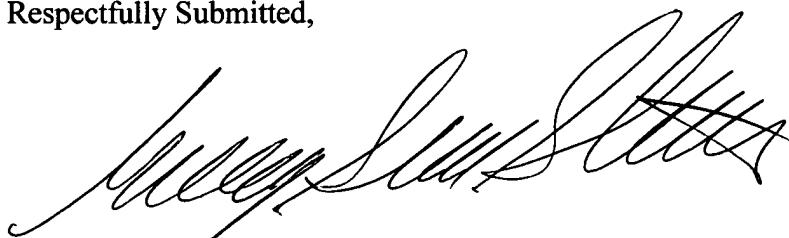
Fujiki does not claim kava reduces the incidence of cancer, provides no data that links kava with a reduced cancer incidence rate in Fiji and states that he has not done any research to support the contention that kava reduces cancer in mammals and therefore established that he does not have a method of use of a compound and therefore could not possibly determine the optimum dosage formulation.

Claims 1-5 were rejected as unpatentable over CA124:220762 under 35 U.S.C. 103(a). However, these compounds are not isomers of the kavapyrones. All kavapyrones have a methoxy group located at position 4 on the pyrone ring and neither of the aforementioned compounds share the same formula. Goniothalamin which is a simple alpha-pyrone that does not have a methoxy group on the pyrone ring and therefore cannot be an isomer of the kavapyrones. This compound is not an isomer of the kavapyrones and because this compound is chemically different it could not be expected to have the same activity and therefore does not render the kavapyrone obvious as an anticancer agent. Claim 1 has been modified to clarify the differences between these compounds.

Double Patenting

The current patent application 10/084,391 was filed as a divisional patent application of patent 09/792,898. The record will note Examiner Goldberg stated that because 09/792,898 contained two difference classes of compounds that the two different classes of compounds needed to be separated into two different patent applications. Only as a requirement of the patent office was the group of compounds listed in 10/084,391 separated from the original patent application and filed as a separate patent application. Patent application 09/792,898 was amended to delete the compounds listed in the new patent application 10/084,391. The nonstatutory double patenting rejection is designed to prevent unjustified or improper timewise extension of the "right to exclude". However, in this case where the patent office places on the inventor a requirement that a second patent application be filed in order for prosecution of the patent application to continue the issue of double patenting cannot apply as intended. If the patent office erred in its requirement of separating the patent application into two applications the inventor will be happy to complete a terminal disclaimer in compliance with 37 CFR 1.321(c) if requested to do so.

Respectfully Submitted,



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DECLARATION UNDER 37 C.F.R. section 1.131

I Gregory Gene Steiner, hereby declare under penalty of perjury as follows:

1. I am the inventor of the subject matter disclosed in the above-referenced patent application.
2. I conceived of the invention of kava as a cancer chemopreventive agent during the period 11-12-97 through 12-17-98, prior to the art references of Fujiki which were cited by the examiner in rejecting claims 1-8 in the office action dated October 30 2005.
3. I began reducing the invention of kava as a chemopreventive agent to practice during the period 11-12-97 through 12-17-98, prior to the publication dates of the prior art reference of Fujiki.
4. I worked diligently to further reduce the invention of kava as an chemopreventive agent during the period 11-12-97 through the filing of my Provisional Patent Application #60/186,688 filed on 03-03-2000, being the provisional application referenced by the subject application and which contains an enabling disclosure of the invention.
5. Accompanying this declaration are true and accurate copies of two pages of notes that I made in my computer journal contemporaneous with the dates shown thereon evidencing my conception and reduction to practice on the invention of kava as an cancer chemopreventive agent that is disclosed and described in my patent application above referenced.
6. Also accompanying this declaration are true and accurate copies of two pages of notes outlining my future studies on the medicinal uses of kava in which it is stated that the concept of kava as a cancer chemopreventive agent was conceived of prior to the initiation of the anticraving studies which were carried out in June of 1999 of which extensive data records are available upon request.
7. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements, and the like made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 3-21-2006


Gregory Gene Steiner

Kava

11-12-97 Meet some people from UH cancer research center who said they spent time in Fiji and talked about drinking kava with the local population after I told them I am studying kava. They were studying why they have low cancer rates in the pacific. They said that Fiji has low cancer rates but did not know why. Thinking about the kava and smoking study it stated they drink a lot of kava in Fiji. When talking to them they said they looked at their diet but could not identify anything that would lower cancer. Could kava have anything to do with cancer? Worth looking into.

1-28-98 When looking at the anticraving activity of kava on the net looked at cancer in the pacific. Found some things published on cancer in the pacific some obviously published by the people I talked with last year but nothing linking kava to cancer. Next step is to get something that deals with kava and cancer.

4-12-98 Could not find anything that links kava and cancer but did find publications dealing with the cancer rates and did find some info on kava but nothing connects the two. Will need to find something that connects the two in some manner. Sounds like work.

6-22-98 Medline search of cancer in the pacific appears to show low cancer in areas known to drink kava. Study looking at cancer in Samoa listed the cancer rates in the pacific- high in Hawaii and NZ but very low in Fiji and Vanuatu. No kava drinking in Hawaii and NZ and lots of kava drinking in Fiji and Vanuatu. If it is possible to find how much kava they consume in the different nations can compare this with the cancer rate to see if they are related.

7-10-98 Found book by Lebot who seems to be the kava guru. He is out of Vanuatu and outlines how much kava is produced and consumed in the various kava drinking nations of the pacific. Just what the doctor ordered. Need to go back and get the cancer rates for these nations and compare.

9-14-98 Cancer stats for the pacific and production and consumption for kava from the 80's. The data is dated but fortunately from the same period. Do a correlation study to see if they are related.

12-17-98 What the hell does that mean. Input of data to produce a scatter diagram just to see if there is any relationship of the data. See if there is any trend in the data. Instead of a scatter diagram the data produced a remarkable curve with near perfect correlation. Spent the day looking at the curve to see it indicates there is nearly perfect inverse correlation between cancer incidence rates and kava consumption. While suspicious of the accuracy of the data derived from various publications they must be remarkable accurate. The curve not only outlines the inverse relationship but the amount of kava consumed and how much needs to be consumed to achieve a related reduction in cancer incidence. Need to find more data points for the graph.

1-08-99 Added more data points to the graph and they fall perfectly on the graph. The graph can be used to determine how much kava consumption is needed to produce an associated reduction in cancer and it can be used to as a predictor for how much cancer will be found when a certain amount of kava is consumed.

4-18-99 Finally collected all available data for cancer rates and kava consumption except Tonga. Could not find cancer rate for Tonga. Correlation coefficient closer to perfect. Need to complete the upcoming anticraving study and then return to write this up for patent and publication.

8-12-99 Writing the patent application not as easy as the books describe. Will do a provisional patent to get the time needed to properly prepare the material and cover the information for when it is published. Need to find someone to review the data and apply a more sophisticated statistical program to ensure accuracy of the results.

12-06-99 Found professor at UH with a dual degree in biology and knows about kava who said he will be happy to review the data.

2-18-00 Professor McClatchy was great and entered the data in his statistical program and produced the same graph. He checked the data with different programs and produced the same curve. Near perfect inverse correlation between kava and cancer. Documents for provisional patent prepared and will refine for submission for publication and utility patent.

Cancer Studies

Clinical

A probable cause for low cancer rates in the South Pacific.

The effects of kavapyrones and morphine on patient comfort, attitude, addiction and treatment outcome in cancer patients with sever pain.

Mechanistic

Kavapyrones and their ability to inhibit the growth and spread of cancer cells.

Kavapyrones as a neuroprotectant in radiation and chemotherapy.

Absorption, distribution and elimination of labeled herbal isotopes.

Blood levels and half-life of selected herbal medicinals.

Addiction Studies

Clinical Studies

Kava as an anticraving agent.

The use of kava for preventing alcohol intoxication.

Mechanistic Studies

Labeled kavapyrones, microlesions and their effect on craving in addicted laboratory animals.

The use functional MRI on craving addicts and the effects of kavapyrones on the neurons associated with craving in the nucleus accumbens.

Goals

To develop effective complimentary and alternative therapies for significant medical problems.

To establish a regional CAM center as a clearing house and resource center for the Pacific Island Nations and the Pacific Rim.

Kava and Cancer

Country	Population	Kava Production	Cancer Rate	Pop/hectare
Vanuatu	168,000	2,500 hectares	71	67
Fiji	770,500	4,200	75	183
W. Samoa	200,000	800	92	250
Micronesia	118,000	300	133	393
NZ Maoris		0	323	
Hawaiians/Polynesians		0	312	
Hawaiians/white		0	335	
Canada		0	286	
Denmark		0	307	
USA/white		0	304	
USA/Black		0	289	
Tonga	103,500	800	?	129